TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS, NORTH AMERICA, INC., Plaintiffs, -v- ALPHAPHARM PTY., LTD. and GENPHARM, INC., Defendants.	:	04 CIV. 1966 (DLC) OPINION AND ORDER

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DENISE COTE, District Judge:

Plaintiffs Takeda Chemical Industries, Ltd., the owner of patents for the widely-sold drug pioglitazone hydrochloride ("pioglitazone"), which is marketed under the brand name Actos, and Takeda Pharmaceuticals, North America, Inc., which sells Actos pursuant to the FDA's approval of its new drug application (collectively "Takeda"), have moved in this patent litigation to compel defendant generic drug companies Alphapharm Pty. Ltd.

("Alphapharm") and Genpharm, Inc. ("Genpharm") to produce all documents concerning patent searches performed and scientific positions formulated by non-legal employees of the defendants' sister company, Generics U.K. This Opinion addresses whether documents reflecting patent searches conducted and analyzed by a generic drug manufacturer are protected by the work product doctrine as documents prepared "in anticipation of litigation" as set forth in Rule 26(b)(3), Fed. R. Civ. P.

Background

In addition to the instant action, Takeda has also brought suit against three other sets of defendants, alleging similar claims for patent infringement and inducement of patent infringement with respect to the patents underlying Actos.[1] In a June 9, 2004 Opinion and Order in one of those actions, this Court described the means by which manufacturers seek FDA approval to market generic drugs, a process that entails filing an Abbreviated New Drug Application ("ANDA"). See Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc., 329 F. Supp. 2d 394, 397-98 (S.D.N.Y. 2004). Familiarity with the June 9 Opinion is assumed, and its discussion of the ANDA process is incorporated herein.

[1] The three other actions are Takeda Chemical Industries, Ltd. v. Ranbaxy Laboratories, Ltd., 03 Civ. 8250(DLC); Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc., 03 Civ. 8253(DLC); and Takeda Chemical Industries, Ltd. v. Watson Pharmaceuticals, Inc., No. 03 Civ. 8254(DLC).

Alphapharm and Genpharm are subsidiaries of Merck Generics, KgaA ("Merck Generics"), as is Generics U.K., a non-party to this litigation. According to the defendants, each of the three subsidiaries have been given "separate responsibilities" for supporting the research, development, marketing, and sale of Merck Generics' pharmaceutical products throughout the world. Of particular importance to this motion, Generics U.K. handles the "investigation" of all patents concerning brand-name pharmaceuticals of interest to Merck Generics.

Having developed an interest in marketing generic pioglitazone in March 2001, based on a projection of the dollar value of estimated sales of the drug and the conclusion that this presented a "sound business opportunity," Merck Generics asked Generics U.K. to investigate its patent status. As with any drug it is investigating for development, Generics U.K. conducted a patent search. When Generics U.K. locates a "blocking patent," Generics U.K. analyzes whether the patent is "acceptable" or whether it is subject to attack as invalid. In the latter instance, it formulates a plan.

Following its customary procedure, Generics U.K. examined an FDA publication known colloquially as the "Orange Book," in which patents that claim an approved or pending use of a new drug are listed, and learned that Takeda is the assignee of U.S. Patent 4,687,777 ("'777 Patent"), which is "directed to the pioglitazone molecule itself." Takeda, 329 F. Supp. 2d at 398-99. Apparently

following additional searches and analysis, Generics U.K. decided that it could attack the '777 Patent as invalid based on a prior patent. On January 29, 2004, Genpharm notified Takeda that Alphapharm had filed an ANDA to market a generic version of pioglitazone and that Alphapharm had certified therein that the '777 Patent was "invalid or unenforceable."[2] Where an ANDA is filed to "obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before [its] expiration," 35 U.S.C. § 271(e)(2), the ANDA constitutes an act of patent infringement as a matter of law. Therefore, the filing of a certification of invalidity invariably leads to litigation, as it did here. On March 12, 2004, Takeda sued Alphapharm and Genpharm, alleging, inter alia, that by filing the ANDA, Alphapharm and Genpharm had infringed upon the '777 Patent under 35 U.S.C. § 271(e)(2)(A).

While Generics U.K. is capable of doing patent searches without assistance from counsel, it has discussed how to conduct patent searches on compounds that Merck Generics intends to market in the United States with Jeffrey A. Hovden ("Hovden"), a partner

[2] As described in the June 9 Opinion, such a certification is known as a Paragraph IV certification. See Takeda, 329 F. Supp. 2d at 397. As defined by statute, a Paragraph IV certification involves certifying that an approved drug's patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

with the United States law firm Frommer, Lawrence, and Haug LLP ("FLH"). In the summer of 2001, Hovden met with Dr. Paul Jenkins ("Jenkins"), who supervises the Generics U.K. team responsible for exploring "intellectual property positions in target markets" on behalf of all Merck Generics subsidiaries (the "Patents Group"), and discussed how the Patents Group carries out its prior art searches and its analysis of that art.[3] In addition, Hovden and Jenkins talked about how "Merck Generics should in the first instance proceed with patent searches regarding compounds that Merck Generics intends to market in the United States." Hovden gave Jenkins specific "instructions" as to how to conduct the patent searches relating to pioglitazone, and in May 2005, Hovden confirmed with Jenkins that the searches for prior art related to pioglitazone "were performed pursuant" to his instructions.[4]

Through a May 17, 2005 letter, Takeda requested an order compelling defendants to produce "all documents concerning patent

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[3] The term "prior art" means "[k]nowledge that is publicly known, used by others, or available on the date of invention to a person of ordinary skill in an art," including "information in applications for previously patented inventions" as well as "information that was published more than one year before a patent application is filed." See, e.g., Black's Law Dictionary 119 (8th ed. 2004).

[4] In their opposition brief, defendants represent that the Patents Group conducted prior art and patent searches relating to pioglitazone between the fall of 2001 and July 2003. They do not cite any affidavits or deposition testimony for this assertion, however, nor does their privilege log supply dates for most of the "summary documents" that defendants produced to memorialize these searches.

searches performed by non-legal employees of Generics U.K. and scientific positions formulated by non-legal employees of Generics U.K." The defendants responded with a May 19 letter in which they asserted that the documents sought by Takeda are "clearly privileged under the work product doctrine" of Rule 26(b)(3), Fed. R. Civ. P. Pursuant to an Order of that date, the parties thereafter submitted briefs as to whether defendants have properly claimed protection under the work-product privilege.

Discussion

Rule 26(b)(3), Fed. R. Civ. P., provides:

> Subject to the provisions of subdivision (b)(4) of this rule, a party may obtain discovery of documents and tangible things otherwise discoverable under subdivision (b)(1) of this rule and prepared in anticipation of litigation or for trial by or for another party or by or for that other party's representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent) only upon a showing that the party seeking discovery has substantial need of the materials in the preparation of the party's case and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means. In ordering discovery of such materials when the required showing has been made, the court shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation.

(Emphasis supplied.)

This portion of Rule 23 codifies the principles concerning the work product privilege enunciated in Hickman v. Taylor, 329 U.S. 495, 510-11 (1947). In United States v. Adlman, 134 F.3d 1194 (2d Cir. 1998), the Second Circuit interpreted for the first time the

phrase "in anticipation of litigation," holding that a document falls within Rule 26(b)(3) where "in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation." Id. at 1202 (citation omitted) (emphasis in original). In adopting this definition of "in anticipation of litigation," the Adlman court noted that "[w]hether it can fairly be said that [a particular document] was prepared because of [an] expected litigation really turns on whether it would have been prepared irrespective of the expected litigation." Id. at 1204. Therefore, in order to win protection for a particular document, the party seeking such protection must prove that it "was created because of anticipated litigation, and would not have been prepared in substantially similar form but for the prospect of that litigation." Id. at 1195 (emphasis supplied). Conversely, documents "prepared in the ordinary course of business or that would have been created in essentially similar form irrespective of the litigation" are not entitled to protection even if they "might also help in preparation for litigation." Id. at 1202.

The defendants do not contend that the withheld materials contain "mental impressions, conclusions, opinions or legal theories of an attorney or other representative" of the defendants, see Rule 26(b)(3), Fed. R. Civ. P., and thus, there is no argument that the documents fall within the most protected category of work

product. The issue is whether the documents are eligible for work product protection, and if they are, whether Takeda has shown a substantial need for the documents. The burden of establishing eligibility is on the defendants, who are the parties asserting the privilege. See United States v. Constr. Prods. Research, Inc., 73 F.3d 464, 473 (2d Cir. 1996).

The defendants have not shown that the patent searches they conducted or the scientific positions they formulated up to the time that they determined that the pioglitazone patent was subject to attack as invalid are eligible for work product protection. The defendants are generic drug manufacturers who are in the business of identifying compounds and manufacturing and selling them. They regularly conduct at least initial patent searches, including those that identify the existence of relevant patents and that shed light on the vulnerability of those patents to an attack of invalidity based on prior art, and do analyses of those searches in the ordinary course of their business. The outcome of these searches and analysis is by no means certain. Rather, the searches and analysis may yield a range of different results and may suggest varied courses of action, most of which do not contemplate, much less provoke, litigation.

For instance, should no "blocking" patent be discovered, then manufacture and sale may proceed without fear of or plans for litigation. Conversely, in the event a "blocking" patent is identified, further searches and analysis will ensue. Where such searches lead to an assessment that the "blocking" patent is valid,

a company may abandon plans for the manufacture of the compound. Alternatively, an assessment that the blocking patent is valid may cause a company to refrain, at a minimum, from filing a Paragraph IV certification and to direct its efforts at marketing the compound only after the patent expires. Only where a search discovers a "blocking" patent and the company determines such patent to be invalid will it file a Paragraph IV certification, which, as noted above, invariably triggers litigation.

A determination that these initial searches and positions are eligible for protection would essentially be a finding that the entire operation of the Patents Group was in anticipation of litigation. That would sweep too broadly. Up until the time a plan was formulated to assert the invalidity of the '777 Patent through a Paragraph IV certification, much of the work of the Patents Group was in the ordinary course of its business and the documents that their work generated would have been created irrespective of litigation. See Adlman, 134 F.3d at 1202.

That a patent search and the development of a scientific position may lead to more than one course of action is evidenced by the conduct of the four sets of defendants in the actions brought by Takeda. Indeed, among these four groupings of generic drug manufacturers, all of whom seek to market generic pioglitazone, only Alphapharm and one other manufacturer, Mylan Laboratories, Inc. ("Mylan"), have challenged the validity of the '777 Patent through Paragraph IV certifications. Compare Takeda Chem. Indus. v. Mylan Labs., Inc., No. 03 Civ. 8253 (DLC), 2005 WL 1457696, at

*1 (S.D.N.Y. June 15, 2005) (stating that Mylan's ANDA certified that the '777 Patent was "invalid on the basis of obviousness due to Compound 16 of [the '200 Patent]"); with Takeda, 329 F. Supp. 2d at 399 n.5 ("Watson is not currently challenging the validity of the '777 Patent"); Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., Ltd., No. 03 Civ. 8250 (DLC), May 7, 2004 Tr. at 8 ("Ranbaxy is not challenging the ['777] patent."). Given this, the defendants' contention that "[o]nce Alphapharm identified the compound patent for pioglitzaone in the Orange Book, all patent searches were performed in anticipation of litigation," presumes too much. It presumes that Alphapharm would press forward whether or not it found that blocking patents existed and whether or not it determined that those patents were valid. The Court will not presume such conduct.

The defendants also contend that any patent search conducted "on the instructions" of an attorney is governed by the work product privilege, citing J.T. Eaton and Co., No. 84 Civ. 4438 (EHN), 1987 WL 17084, at *2 (S.D.N.Y. Aug. 31, 1987) and Golden Trade, S.r.L. v. Jordache, 143 F.R.D. 508, 511 (S.D.N.Y. 1992). Unlike the searches undertaken in those cases, however, the searches at issue here were undertaken on the instruction of executives at Merck Generics, and not because outside counsel for the firm ordered them to be done. The fact that outside counsel apparently gave some advice about the process to use in conducting

searches does not clothe those searches with protection.[5]

Even assuming that Golden Trade, 143 F.R.D. at 508, is still good law, it can be distinguished from the instant case for another reason. As that opinion clearly explains, the prior art search at issue in that case was conducted by the plaintiff patent holders "at a time when [they] had already been sued in two federal courts by apparel manufacturers that apparently were seeking declarations of invalidity against the patent." Golden Trade, 143 F.R.D. at 509-10. Less than two weeks later, the plaintiffs brought a related action of their own. Id. at 510. The same is not true in the instant action, where the patent searches were conducted well before any litigation and before Alphapharm even determined whether or not to file an ANDA. As a result, the defendants' claim of privilege as to these documents cannot be sustained. Because the documents are not eligible for work product protection, it is unnecessary to determine whether Takeda has shown a substantial need for the documents or whether Rule 26(b)(3) applies to the documents held by a non-party who is related to a defendant.

[5] It is difficult to glean precisely what outside counsel conveyed to Merck Generics in connection with its patent searches. It may have been as innocuous as advice about the most effective way to conduct a search of U.S. patents. Whatever it was, the defendants have not presented evidence that the attorney himself requested any search of pioglitazone patents to be performed.

Conclusion

For the reasons stated above, Takeda's motion to compel production of documents relating to the results of patent and prior art searches performed by Generics U.K. in relation to the '777 Patent, including the scientific positions formulated, is granted. With respect to any documents created after the defendants determined that the '777 Patent was subject to attack as invalid, those documents may very well be eligible for Rule 26(b)(3) protection. Without a more detailed privilege log,[6] however, Takeda cannot analyze whether or show that it has a substantial need for the documents. The defendants shall provide a revised privilege log within five business days.

SO ORDERED:

Dated: New York, New York
July 19, 2005

DENISE COTE
United States District Judge

[6] For many documents, defendants' privilege log does not identify the type of document or the dates on which it was produced, identify a person associated with the document, or provide an adequate summary of the document. See S.D.N.Y. Local Civ. R. 26.2(a)(2)(A).